TERRA PURE SPA COLLECTION FRESH ALOE HAND SANITIZER- alcohol gel Yangzhou Eco-Amenities CO., Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Terra Pure Spa Collection Fresh Aloe Hand Sanitizer

Drug Facts

Active ingredient

Ethanol (Alcohol)75% v/v

Purpose

Antiseptic

Use

hand sanitizer to help reduce bacteria on the skin

Warnings

for external use only:hands

Do not use

in children less than 2 months of age.

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or redness occurs.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- For children under 6, use only under adult supervision.

Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Water, Dichlorobenzyl alcohol, Acrylates/C10-30 alkyl acrylate crosspolymer, Triethanolamine, Methyl Gluceth-20, Glycerin, Aloe Barbadensis Leaf Juice, Tocopherol, Fragrance, FD&C Yellow

Package Labeling





PMS 7546 C

TERRA PURE SPA COLLECTION FRESH ALOE HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77849-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICHLOROBENZYL ALCOHOL (UNII: 1NKX3648J9)	

TROLAMINE (UNII: 9O3K93S3TK)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:77849-004-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/15/2020	

Labeler - Yangzhou Eco-Amenities CO., Ltd (543786608)

Revised: 8/2020 Yangzhou Eco-Amenities CO., Ltd